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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,730	09/16/2005	Evert Johannes Bunschoten	0470-050738	1144

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William H Logsdon
Webb Ziesenheim Logsdon Orkin & Hanson
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818

EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
06/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,730	BUNSCHOTEN ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,20,21,25-28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 20, 21, 25-28, and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on March 18, 2010. Claim(s) 17, 20, 21, 25-28, and 30 and are examined herein.

Response to Arguments

Applicants arguments with respect to the 103(a) rejection of claims 17, 20, 21, 25, 26, 28, and 30 as being unpatentable over (Lardy (WO 01/23405) of record in view of Murray (US Patent No. 2,793,216) have been fully considered but are not persuasive.

Applicants arguments with respect to the 103(a) rejection of claim 27 as being unpatentable over (Lardy (WO 01/23405) of record in view of Murray (US Patent No. 2,793,216) as applied to claims 17, 20, 21, 25, 26, 28, and 30 above in further view of Place (US Patent 6,117,446) of record have been fully considered but are not persuasive.

Applicants contend that Lardy discloses a number of substances and casually suggests that all the compounds would be orally active or bioavailable. This is not persuasive. Although Applicant argues that a number of the compounds that are taught by Lardy are not active, Lardy teaches several compounds that are orally active. As set forth on record in the previous office action, Lardy teaches, though not by way of specific example of 15-hydroxytestosterones, nonetheless a generic compound that encompasses said compound, the oral formulation of compounds that are

encompassed by the formula. Examiner is fully aware that Lardy teaches a number of possible compounds that are encompassed by this generic formula and that is the reason the Murray reference is employed. Murray specifically teaches 15-hydroxytestosterones. Further, Murray teaches that these compounds exhibit pharmacological activity. Applicants argue that Murray provides no data to backup this contention, however, it is the opinion of the Examiner that this would be sufficient evidence to a person of ordinary skill in the art to at least try to formulate 15-hydroxtestosterones into an oral formulation with a reasonable degree of success.

The rejections of the previous office action are hereby maintained for reasons of records and are included below for Applicants' convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 20, 21, 25, 26, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Lardy (WO 01/23405) of record in view of Murray (US Patent No. 2,793,216).

Lardy teaches a method of treating androgen responsive diseases comprising administering compounds of formula 1 (page 3, line 29-page 4, line 19; claim 1).

Lardy teaches the typical dose administered to the subject ranges from 0.03 to about 30 mg/kg per day (page 30, lines 27-29). Formulations are suitable for buccal or sublingual administration including lozenges comprising the active ingredient (page 31, lines 27-28; page33, lines 19-21).

Although Lardy teaches a generic formula which encompasses 15-hydroxytestosterones, the reference does not specifically teach 15-hydroxytestosterones, nor the α and β isomers, thereof.

Murray teaches the synthesis of 15-hydroxytestosterones. Furthermore, Murray teaches that the instant compounds (claim 1 and 2) and that they exhibit pharmacological value (column 4, lines 11-15).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the compounds encompassed by formula 1 in oral formulations for the treatment of androgen responsive disease as taught by Lardy and

employed 15-hydroxytestosterone. The motivation, provided by Murray, teaches that 15-hydroxytestosterones have pharmacological activity, therefore it would be obvious to one of ordinary skill in the art to formulate an oral dosage unit comprising 15-hydroxytestosterone. Further, it would be obvious to employ these compounds in the treatment of androgen deficient ailments. The fact that Lardy generally teaches the compounds for treating androgen responsive diseases and Murray specifically teaches the compounds as possessing pharmacological activity would motivate one of ordinary skill in the art to expect, with a reasonable degree of success, that 15-hydroxytestosterones would also have the potential to treat androgen deficient ailments.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have known that because Murray teaches 15-hydroxytestosterones that the compound contained a mixture of both the α and β isomers: 15α-hydroxytestosterone and 15β-hydroxytestosterone. Isolation and separation of isomers of a known racemate is prima facie unless there are "unexpected results," See *In re May*, 197 USPQ 601; *In re Adamson*, 125 USPQ 233; *Brenner vs Ladd*, 147 USPQ 87.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over (Lardy (WO 01/23405) of record in view of Murray (US Patent No. 2,793,216) as applied to claims 17, 20, 21, 25, 26, 28, and 30 above in further view of Place (US Patent 6,117,446) of record.

Lardy and Murray are discussed above. Lardy teaches that the composition can comprise an additional active agent (claim 6).

Neither Lardy nor Murray teach the additional agent as being progestin and/or estrogen.

Place teaches a buccal drug delivery system that may be used in female hormone replacement therapy, in female contraception and to treat female sexual dysfunction (abstract). Place teaches that the pharmaceutical compositions comprise a therapeutic amount of an androgenic agent, a progestin, an estrogen, and a bioerodible polymeric carrier (column 4, lines 4-11).

Place further teaches that the buccal dosage units are in the form of tablets in amounts of 0.1 to about 2.5 mg of the selected androgenic agent, about 300 to 5000 μg progestin and about 50 to 500 μg estrogen (column 11, lines 42-50).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the 15-hydroxytestosterone formulations with an additional agent as discussed above by Lardy and also added to the formulation estrogen and/or progesterone. The motivation provided by Place teaches that oral formulations comprising androgenic agents can also be combined with progesterone and/or estrogen.

Conclusion

Claims 17, 20, 21, 25-28, and 30 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627